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EXAMINER

BABIC, CHRISTOPHER M

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/602,998

Applicant(s)

BRENNAN ET AL.

Examiner

Christopher M. Babic

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1-13 and 15 are pending. The following Office Action is a FINAL rejection in response to Applicant's response dated February 9, 2006.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1 and 15 remain rejected under 35 U.S.C. 102(b) as being anticipated by Monforte et al. (U.S. 5,700,642).

Regarding Claim 1, Monforte et al. teach cleavable oligonucleotide primers that are immobilized to a solid support (Columns 31-32, Example 2). Intended use phraseology such as, "...for performing...", is not considered to further limit the scope of the claims.

Regarding Claim 15, Monforte et al. teach photocleavable linkages (Column 24, Lines 57-67).

Response to Arguments - 35 USC § 102

Applicant's amendments and arguments filed February 7, 2006 have been fully considered but they are not persuasive.

Applicant argues that Monforte fails to teach a solid support for performing a plurality of polynucleotide amplification reactions that comprises a releasable primer for each amplification reaction, wherein said primer is immobilized on a surface of said solid support, *and is adapted to be released before, during or after the amplification reaction*. The instant amendment presented by Applicant is written in alternative language that encompasses wherein a primer can be released at any time before, during *or* after the amplification. Thus, as Applicant highlights, Monforte's primers *can be cleaved after amplification*, and therefore anticipate the instant claim language.

Applicant further argues that Monforte fails to teach the instant invention because Monforte teaches that only a fragment of the primer is actually released. Applicant is correct in asserting that Monforte teaches that a fragment of the primer is released, however, the instant claim language presents "a cleavable primer", which is encompassed by the teachings of Monforte. The releasable oligonucleotides taught by Monforte may still act as a primer for synthesis, and thus, anticipate the instant claim language. Furthermore, Applicant is reminded that instant claim language does not include any limitations that require the *entire* oligonucleotide primer to be released.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 2-13 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Rava et al (US 5,545,531) and Monforte et al. (U.S. 5,700,642).

Regarding Claims 2 and 3, Rava et al. teach supports for processing multiple chip assays (Abstract). In particular, Rava et al. teach the following:

(a) a first solid support; wherein the surface of said comprises a plurality of derivatized areas; wherein one or more primers are immobilized on a derivatized area of said first solid support (Rava et al. teach a biological chip plate comprising a wafer including a plurality of biological arrays wherein the arrays are a collection of

oligonucleotides, at least two of which are different, arranged in a spatially defined manner; Fig 4; Column 2, Lines 62-67; Column 4, Lines 1-19; Column 8, Lines 1-11, Rava et al. teach surface immobilized oligonucleotides on a functionalized substrate containing derivatized areas, preferably glass or silica; Fig 8; Column 3, Lines 39-48; Column 9, Lines 29-29 and 36-37).

(b) a second solid support wherein said support comprises a plurality of wells and each well corresponds to a primer for each target nucleic acid (Rava et al. teach a biological chip plate comprising a plurality of wells, the walls of each well surrounding and enclosing the probe array of a biological array, i.e. corresponding to a primer for each target nucleic acid; Figs 4, 5, and 6; Column 4 Lines 19-25; Column 8, Lines 1-16; Column 8, Lines 40-45).

Intended use phraseology such as, "...for amplifying...", is not considered to further limit the scope of the claims.

Regarding Claim 4, Rava et al. teach sequencing large quantities of DNA; therefore Rava et al. anticipate pluralities of subsequences of polynucleotides (Column 11, Lines 43-46).

Regarding Claim 5, Rava et al. teach glass as a biological chip substrate (Column 4, Lines 5-7).

Regarding Claim 6, Rava et al. teach covalent immobilization (Column 9, Lines 13-67; Column 10, Lines 1-9).

Regarding Claim 8, Rava et al. teach nucleic acid probes; therefore Rava et al. teach cleavable moieties (i.e. part of the nucleic acid) (Column 3, Lines 39-67).

Regarding Claim 10, Rava et al. teach solid support surfaces with Si-OH functionalities; therefore Rava et al. teach hydrophilic areas (Column 9, Line 50-52).

Regarding Claim 11, Rava et al. teach an example with a feature size of about 100 microns on a side which would give an array with 10,000 probe addresses per 1 cm²; therefore Rava et al. anticipate a density of derivatized areas of 10 to 10,000 per cm² (Column 10, Lines 38-40).

Regarding Claim 12, Rava et al. teach a probe array size of 0.25 mm²; therefore Rava et al. anticipate the size of a derivatized area on a solid support that is between 10⁻³ to 5mm² (Column 9, Lines 21-24).

Regarding Claim 13, Rava et al. teach a probe array with 10⁵ features; therefore Rava et al. anticipate a number of derivatized areas on a solid support between 10⁻³ to 500,000 (Column 9, Lines 21-24).

Rava et al. teach supports for processing multiple chip assays, but do not teach primers, non-covalent immobilization, or photocleavable moieties.

Regarding Claim 2, Monforte et al. teach primers (i.e. 3' terminal ends free to participate in primer extension reactions) immobilized to a solid support (Columns 31-32, Example 2)

Regarding Claim 3, Monforte et al. teach forward and reverse primers immobilized to solid support in amplification reactions (Column 5, Lines 13-49).

Regarding Claim 7, Monforte et al. teach non-covalently attached oligonucleotides to a solid support in a solid phase nucleic acid amplification method (Column 19, Lines 60-67; Column 20, Lines 1-10).

Regarding Claim 9, Monforte et al. teach photocleavable primers (Column 24, Lines 57-67).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of invention to have used the primers of Monforte et al. in the Rava et al. biological chip plate. The motivation to do so, provided by Monforte et. al, would have been that these primers helped to improve sequencing and size information for primer extension products (Column 8, Lines 40-46).

Response to Arguments - 35 USC § 103

Monforte and Rava teach and/or suggest all limitations set forth in Claims 2 and 3. Please see explanations above.

Conclusion

Claims 1-13 and 15 are rejected. No claims are allowed.

THIS ACTION IS MADE FINAL.

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 571-272-8507. The examiner can normally be reached on Monday-Friday 7:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 1637

Christopher M. Babic

Patent Examiner

AU 1637

Ch M Babic 2/21/06

Kenneth R. Horlick
KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER

2/21/06